



# The FDA as Portrayed in Fiction: Incompetent Bureaucracy or Effective Vanguard of Public Health?

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Charlotte Wasserstein

**THE FDA AS PORTRAYED IN FICTION: INCOMPETENT BUREACRACY OR**  
**EFFECTIVE VANGUARD OF PUBLIC HEALTH?**

Class of 2011

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## **Abstract**

This paper will discuss how the Food and Drug Administration (“FDA”) is portrayed in fiction. The seven novels discussed here<sup>1</sup> have been selected because FDA decisions and policies are crucial to each of their plots. This paper is not intended to offer an exhaustive look at how the FDA is depicted in literature, but rather to show how these narratives, through their characters and their personal tribulations, illuminate certain strengths and weaknesses of current FDA practices in a more vivid and personal way than traditional legal analysis. The paper is divided into four sections. First, this paper will discuss some systemic problems within the FDA regulatory process, as identified by these novels. Second, this paper will discuss the way these novels portray personnel issues faced by the Agency. Third, this paper will discuss the novels’ depiction of the FDA’s successes. Fourth, this paper will comment on the utility of using fiction as a lens through which to study a government agency such as the FDA. A plot summary of each novel is attached as Appendix A.<sup>2</sup> Attached as Appendix B is a list of the best available sales data for each book.

## **Introduction**

The diversity of the products featured in these novels illustrates the enormous task faced by the FDA as it seeks to regulate food and drugs in the American marketplace. Five of the novels center on medicinal drugs<sup>3</sup>, one discusses futuristic nanotechnology-based medical

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<sup>1</sup> CARL DJERASSI, *NO* (1998); GARY BRAVER, *FLASHBACK* (2005); JOHN R. MAXIM, *THE SHADOWBOX* (1996); MICHAEL PALMER, *MIRACLE CURE* (1998); JOAN JOHNSTON, *THE PRICE* (2003); JONATHAN JAVITT, *CAPITOL REFLECTIONS* (2008); EDWARD LERNER, *SMALL MIRACLES* (2009).

<sup>2</sup> While the plot summaries have been provided at the end of the paper, the reader might wish to skim them before reading it, as they provide useful background information about the stories and characters discussed.

<sup>3</sup> DJERASSI, *supra* note 1; BRAVER, *supra* note 1; MAXIM, *supra* note 1; PALMER, *supra* note 1; JOHNSTON, *supra* note 1.

devices<sup>4</sup> and one focuses on genetically modified (“GM”) food.<sup>5</sup> Further, these novels show the wide variety of crimes the FDA must guard against: three involve fraudulent drug testing results submitted to the Agency<sup>6</sup>, one centers on harm caused by a side effect that did not arise during clinical testing<sup>7</sup>, one involves counterfeit and adulterated drug trafficking<sup>8</sup>, one discusses the intricacies of getting a drug from the lab to the marketplace<sup>9</sup>, and one depicts the sale of dangerously addictive GM food.<sup>10</sup> Given that the FDA’s jurisdiction spans a such diverse array of misfeasance involving a large assortment of products, it is not surprising that the books all depict the FDA as struggling to manage the task set before them, especially given that the Agency is portrayed as buffeted by political pressure from without and battling corruption and inefficiency from within.

The first section of this paper discusses six systemic challenges facing the FDA, as uncovered in these novels: a) the large investment of time and money required to test new drugs; b) bureaucratic red tape and fragmentation of lawmaking; c) lack of enforcement of laws and regulations; d) difficulties arising out of risk analysis; e) the influence of money in FDA procedures and f) balancing the competing goals of promoting competition and protecting public safety.

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<sup>4</sup> LERNER, *supra* note 1.

<sup>5</sup> JAVITT, *supra* note 1.

<sup>6</sup> JOHNSTON, *supra* note 1; PALMER, *supra* note 1; BRAVER, *supra* note 1.

<sup>7</sup> LERNER, *supra* note 1.

<sup>8</sup> MAXIM, *supra* note 1.

<sup>9</sup> DJERASSI, *supra* note 1.

<sup>10</sup> JAVITT, *supra* note 1.

## **I. FDA AS VILLAIN: SYSTEMIC PROBLEMS**

**A. These novels portray FDA drug testing requirements as unnecessarily costly and time-intensive.**

*“Many times a manufacturer can correct a problem with a drug or piece of equipment in just a few weeks. But if the bureaucracy in Washington or the FDA in Rockville gets a hold of something, it could take years.”<sup>11</sup>*

In Michael Palmer’s *Miracle Cure*, a Boston drug company claims to have developed a pill called Vasclear that cures heart disease. Before the company can sell this drug, they must run it through the three phases of clinical testing required by the FDA for approval of their new drug application (“NDA”). The time and expense of the standard procedure is onerous, as illuminated by the following exchange in the novel between a senator and the FDA commissioner during a senate hearing:

Senator: “...how long does it take for a new drug to make it to the public?”

FDA commissioner: “...from beginning to end, the process can take from five to as long as ten years or even more, and cost upward of one hundred and twenty five million dollars.”<sup>12</sup>

The book shows the frustration of the drug company as it struggles to develop the new drug without going bankrupt, the impatience of doctors anxious to try the new medicine (which could replace risky and costly heart surgery procedures), and the anguish of patients who seek a ‘miracle cure,’ as the title denotes, for loved ones stricken with heart disease.

One solution sought by Vasclear’s purveyors is to get the FDA to “fast-track” the drug. Similarly, in Gary Braver’s *Flashback*, the doctor assigned as “chief principal investigator” for a new Alzheimer’s pill emphasizes the need for NDA fast-tracking to the press and his

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<sup>11</sup> PALMER, *supra* note 1, at 121.

<sup>12</sup> *Id.* at 65.

coworkers.<sup>13</sup> In both of those novels, the drugs at issue could be life-saving, a factor that weighs in favor of fast-tracking. Fertility drugs, such as those at issue in *NO* by Carl Djerassi, do not fall into the “life-saving” category, and must follow the standard FDA testing timeline. Thus, in *NO*, a biotech start-up executive bitterly complains of the testing requirements: “the FDA indulged in its usual overkill.”<sup>14</sup>

These novels illuminate another problem resulting from the huge amounts of time and money necessary to complete NDAs: drug companies have an incentive to conceal problematic test results from the FDA. In *Small Miracles* by Edward Lerner, set in 2016, a biotech company has devised a “nanobot” suit, which protects the wearer from harm by injecting lifesaving nanobots (microscopic robots), into the bloodstream to provide medical assistance at the cellular level. The nanobots are supposed to disintegrate into the bloodstream after their job is done, but the protagonist, Brent, learns the hard way that the nanobots are malfunctioning. Instead of disappearing after curing him, the bots take over Brent’s mind and attempt to spread to other humans to create a new race of nanobot-controlled humans. The company developing the nanobots learns of this problem while FDA-required testing is still on-going, but they do not report the problem, because “[a]ny change to the nanobot physical design... puts us back to Square One with the FDA.”<sup>15</sup> As illustrated by this story, worries that the FDA will overreact and require prohibitively expensive new testing disincentives drug companies from exposing flaws in their drugs, for fear that a small defect will scuttle the whole application. However, as in both *Small Miracles* and *Miracle Cure*, these testing flaws can be indicative of a serious problem with the new drug, and while it might be frustrating for companies seeking to profit from sales of

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<sup>13</sup> BRAVER, *supra* note 1, at 84, 172.

<sup>14</sup> DJERASSI, *supra* note 1, at 217.

<sup>15</sup> LERNER, *supra* note 1, at 125-6.

new drugs, in both novels the FDA's strict testing requirements protect the public from dangerous drugs and technology.

**B. These novels portray the FDA as hampered by bureaucratic red tape and fragmentation of lawmaking.**

*"But there's a much better, more efficient, and certainly more cost-effective way of doing it than relying on what may be the most inept, bureaucratically snarled agency in the entire government."*<sup>16</sup>

Even leaving aside the NDA testing requirements, these novels portray the FDA as hampered by bureaucratic, internal red tape. Describing the skills needed to do well at her job as an FDA epidemiologist, Gwen, the protagonist of Jonathan Javitt's *Capitol Reflections* notes: "Constant diligence – and the patience to withstand endless bureaucratic meetings – could be draining."<sup>17</sup> Later in this same novel, a talented public health official who was unsuccessfully nominated for FDA commissioner says to Gwen, as he assists her in foiling a plot involving dangerous GM coffee: "If I'd been confirmed as FDA commissioner, I might have been far too busy to help you now."<sup>18</sup> As exemplified by these quotes, these novels depict red tape and bureaucracy as hindering the FDA's ability to efficiently police the dangerous products that the books' villains, profit-obsessed food and drug corporations, seek to insert into the marketplace.

However, the Agency's attention to detail is also sometimes shown to be a strength. In Gary Braver's *Flashback*, a doctor says to the heroine René, a young pharmacological consultant investigating abnormal trial results, "You know how anal the FDA is about protocol. One hint of impropriety and Memorex would be back-burnered for years."<sup>19</sup> Considering that Memorex was causing patients to suffer debilitating flashback hallucinations, the FDA's strict adherence to

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<sup>16</sup> PALMER, *supra* note 1, at 123.

<sup>17</sup> JAVITT, *supra* note 1, at 11.

<sup>18</sup> *Id.* at 318.

<sup>19</sup> BRAVER, *supra* note 1, at 139.

protocol was in fact the only thing that prevented the harmful drug from reaching the public, providing the story with a happy ending.

Another problem within the FDA bureaucracy identified in these novels is a fragmentation of lawmaking. As a senator explains during a news interview in *Capitol Reflections*, attempting to minimize the FDA's mandate to regulate GM foods, "The EPA evaluates a genetically modified plant for environmental safety. The USDA determines if the plant is safe to grow. Lastly, the FDA decides whether or not the plant is safe for consumption in food products."<sup>20</sup> Each agency in this chain, the novel shows, has too narrow a focus to impede the criminal activities of a company selling GM coffee, grown to be extra addictive. While the FDA eventually halts sales of the GM coffee after it causes fatal seizures, it is largely because so many agencies are involved that the crime goes undetected for so long. Each agency assumes another is on the lookout for the dangers that may arise from GM foods. Fragmentation of lawmaking is part of the explanation for another FDA challenge addressed in these novels: a lack of enforcement of existing laws and regulations.

**C. These novels portray the FDA as lacking the resources needed to effectively regulate food and drugs.**

*[Two gangsters chew over why it's easier to profit from illegal sales of counterfeit prescription drugs rather than sales of illegal narcotics:]*

**Gangster 1:** "You don't have 3,000 DEA agents kicking doors in all over the world [or] 2,000 FBI agents who work full time on illegal drugs. You don't have the coast guard stopping boats at sea or the air force tracking planes. You don't have dogs sniffing luggage at airports... You don't even have the regular local cops because this is strictly the FDA's jurisdiction. The FDA can call in the FBI but unless it's high profile the FBI won't get excited."

**Gangster 2:** "What do you have?"

**Gangster 1:** "In the FDA? Maybe thirty-five full-time, unarmed criminal investigators."

**Gangster 2:** "For the whole country?"

**Gangster 1:** "For the whole world."<sup>21</sup>

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<sup>20</sup> JAVITT, *supra* note 1, at 103.

<sup>21</sup> MAXIM, *supra* note 1, at 109.



In John R. Maxim's *The Shadowbox*, investment banker Michael Fallon gets caught up in a violent plot to sell counterfeit prescription drugs. Drug companies, lawyers and gangsters all work together to the extent that, according to the novel, fifty percent of the nation's drugs are counterfeit. This could mean that they are identical to the real drug in both appearance and effect, or, it could mean that the drug is dangerously adulterated. Either way, it is illegal to produce or sell such drugs, as they skirt the FDA's drug testing requirements. Unlike in *Capitol Reflections*, where a lack of laws regulating GM food allowed companies to profit from harming the public, here, the problem is not a lack of law but a lack of enforcement. One reason the novel offers to explain why the conspiracy in *The Shadowbox* goes unpunished for decades is the FDA's lack of resources (such as money or employees), and consequent inability to enforce the laws it administers.

These novels show how budgetary woes of the FDA are compounded by the timeline of drug approvals. The drug companies in these books often trick the FDA into approving their drug using faulty trial data, and then rely on the fact that the FDA will be reluctant to expend the huge amount of money, and credibility, required by a recall, if a flaw is discovered post-approval. For example, says a frustrated doctor in *Miracle Cure*, trying to prevent FDA approval of a flawed heart drug:

“...the key to the whole thing is that once a drug is on the market, it's incredibly difficult to get it off. And it's virtually impossible to get a drug recalled just because it doesn't work. In fact, most of the drugs on the market today don't work all that well... Nobody in research or even at the FDA has the time or interest to run studies or follow-up research on most of these medications as long as they don't hurt anyone. That's the key.”<sup>22</sup>

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<sup>22</sup> PALMER, *supra* note 1, at 372.

It is not coincidental, then, that four of these novels center on attempts to prevent FDA approval of a dangerous drug, and in only one does the hero seek the remedy of a drug recall, as the FDA's enforcement capabilities seem to taper off post-approval.

However not all of these novels portrayed FDA enforcement as ineffectual. For instance, René says to a nurse near the beginning of *Flashback*, before she realizes just how dangerous Memorex is:

“If word got out to the state and federal regulatory boards that there are irregularities in the medical records of a patient arrested for murder, that critical pharmaceutical documentation is missing or locked away... we could see a SWAT team of regulators come down on us like banshees[.]”<sup>23</sup>

In fact, four of these novels rely on the FDA's enforcement tactics, including the NDA testing requirements, as a crucial element in stopping the various criminal forces attempting to harm the American public.

These stories suggest that under-enforcement is not caused merely by a paucity of FDA resources, but could also be an inevitable result of the fact that the Agency must make enforcement decisions based on risk analysis. Unlike, say, a district attorney trying to prosecute someone for murder, where the accused is either guilty or innocent, the FDA must consider whether a food or drug product's risk of harm is sufficiently serious, unavoidable and widespread to warrant removing it from the market, despite its countervailing benefits. In *Small Miracles*, the CEO of a nanotechnology company is loath to disclose a hiccup in the design of their nanobot to the FDA, because, he speculates:

“Look at their choices. They could slap us with a desist order, in the name of safety – very straightforward. No bureaucrat ever lost his job by not taking a risk. Or they could take the time to think through a complicated situation. Which choice gets the issue off their desks and them out the door [faster]?”<sup>24</sup>

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<sup>23</sup> BRAVER, *supra* note 1, at 61.

<sup>24</sup> LERNER, *supra* note 1, at 157.

He fears that the FDA will over-enforce the drug safety laws, in the sense that they would shut down testing and production of an enormously useful technology because of a minor, fixable defect. The data necessary to show that a drug is unsafe is often complicated, and this CEO's worries show that this complexity, and the sophisticated investigators required to parse it, could lead to the FDA "playing it safe" by unnecessarily denying approval of a potentially life-saving product, just because it presents a small, hard to analyze safety risk. That the FDA must base policy choices on risk analysis has broader implications than just over- or under-enforcement of the laws, however.

**D. These novels portray the FDA as struggling to perform risk analysis and analyze complex statistical data.**

*"[I]f it became known that she was a subject in the clinical trials of a drug which may have made possible her escape... It would almost certainly mean the termination of the development of a cure for Alzheimer's disease."*<sup>25</sup>

Even when Dr. Brian Holbrook, the hero of *Miracle Cure*, has test results in hand showing that the drug Vasclear is not as effective as its developers claim, he laments, "My connection at the FDA says they can't make any move at all against Vasclear without absolute proof."<sup>26</sup> In the context of medicine safety, "absolute proof" consists of complex statistical data, and also policy choices. All drugs have side effects, many of them serious. If these side effects are overly emphasized to the FDA during a drug's testing period, it might delay or prevent the approval of a drug that would otherwise save lives. The FDA faces the challenge of deciding when a drug's disadvantages outweigh its benefits, and unlike the drug companies, the Agency is supposed to balance the risks and benefits of a drug without taking into account the economic benefits the drug could provide to its manufacturers. The FDA must focus solely on what is best

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<sup>25</sup> BRAVER, *supra* note 1, at 122.

<sup>26</sup> PALMER, *supra* note 1, at 312.

for the American public. This task is complicated by the possibility that serious side-effects could surface only after the drug has been approved, perhaps because testing should have used a larger sample size, or on account of a disease's latency period.

This delicate balancing act, wherein the FDA must decide what amount of risk is acceptable for a new drug to be approved, is brought into sharp relief in these novels because many of the characters have deeply personal investments in the outcome of the FDA's decision. In *Flashback*, heroine René Ballard's father died a slow, agonizing death of Alzheimer's disease; she is thus hesitant to alert the FDA of problems she sees with a new Alzheimer's drug, because she wishes so badly for a pill that would spare others the grief the disease wrought upon her family. In Joan Johnston's *The Price*, a lawyer who exposes his own law firm's plot to conceal problematic test results for a diabetes drug has ample incentive to investigate thoroughly: his own daughter takes the medicine. In *Miracle Cure*, Dr. Brian Holbrook's father refuses a second heart procedure after a first goes awry, and Brian exposes a new heart drug to be a fraud despite his most fervent hope that such a pill could exist, and save his father's life.

The dilemmas faced by these characters, whether to permit a drug to enter the marketplace because it will provide relief to many, despite the fact that it will cause harm to some, is one the FDA must grapple with daily. As these stories show, there are no easy solutions. Yet these novels generally come down on the side of safety, at least in part because of a suspicion that the FDA regulatory process is influenced too much by those seeking to maximize something other than public health: profits.

**E. These novels portray FDA procedures as overly influenced by financial considerations.**

*“Doctors get paid thousands of dollars for each patient they enroll in a trial, plus research grants, equipment upgrades, staff support, travel perks, plus stock options in the company. With all those incentives, it’s hard to write up a negative report to the FDA.”*  
*“Except actual scientific results don’t lie.”<sup>27</sup>*

The drug industry generates massive profits, such that securing FDA approval of a new drug can determine the economic fate of a whole company. A news segment in *Flashback* about the Alzheimer’s drug at issue in the novel brings this point home: “If approved by the FDA, all indications point to Memorine becoming one of the all-time blockbuster drugs with first-year sales of five billion dollars.”<sup>28</sup> The sum of five billion dollars is not out of the range of what a real drug company could earn yearly from a new wonder drug.<sup>29</sup> The enormity of the profits that companies stand to make if their products are approved by the FDA can create perverse incentives. Drug companies themselves report NDA clinical testing results to the FDA. Given the riches that could follow NDA approval, companies have ample incentives to hide data anomalies.

Further, the novel *NO* shows how FDA approval can not only determine the fate of extant drug companies, but whether such companies form in the first place. In *NO*, a biotech firm needs investors so they can develop a new fertility drug, and they need to get funding before FDA approval so as to pay for the tests required to obtain it. FDA requirements and documentation are key components of the company’s initial public offering documentation. As the company lawyer says during a board meeting, “Sales cannot start until we get FDA approval – as I tried to make

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<sup>27</sup> BRAVER, *supra* note 1, at 93.

<sup>28</sup> *Id.* at 173.

<sup>29</sup> See, e.g., Duff Wilson, *Drug Firms Face Billions in Losses in '11 as Patents End*, N. Y. TIMES, March 6, 2011, at A1 (describing Pfizer’s ten billion dollar per year revenue stream from one drug, Lipitor).

ferociously clear in our prospectus.”<sup>30</sup> Of course, the fact that FDA requirements dictate a company’s success or failure is not necessarily a bad thing – it could just mean that the Agency is doing its job. However, because the financial stakes are so high, companies could be more likely to look for ways to circumvent the requirements so as to ensure that the money spent developing a drug wasn’t wasted if the FDA denies approval. In *NO*, the company follows regulations to the letter and eventually reaps a handsome profit; in short, the novel gives a realistic portrayal of a biotech company’s successful formation within the current regulatory scheme. But in *Flashback* and *Miracle Cure*, the drug companies cut corners and deceive FDA regulators in an effort to tap into the profits that could flow from a new FDA-approved medicine.

It might seem as though profit-motivated manipulation of the FDA regulatory system could be deterred by lawyers, either in the form of plaintiffs’ firms representing injured drug users, or, defense firms charged with ensuring that their client drug companies follow the FDA regulations. Plaintiffs’ firms do, indeed, expose and prosecute some drug company malfeasance, providing some deterrent effect. Joan Johnston’s novel *The Price* involved a wrongful death class action suit filed by the parents of children harmed by a flawed diabetes drug, and it was only as a result of the suit that the conspiracy was exposed. But, as one gangster put it in *The Shadowbox*, “Lawyers are for talking to *after*. Talk to them *before* and you never get anything done.”<sup>31</sup> In other words, while lawyers might be able to help victims receive compensation for harm done at the hands of drug companies who skirted FDA requirements, they generally cannot prevent the harm from occurring in the first place.

In *The Price*, the villain is not the drug company, but the law firm representing it. This novel tells of a firm whose revenues are dependent on one large client: Hyland Pharmaceuticals.

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<sup>30</sup> DJERASSI, *supra* note 1, at 212.

<sup>31</sup> MAXIM, *supra* note 1, at 106 (emphasis in original).

Hyland produced a drug, D-Free, that allowed diabetes sufferers to forgo painful and invasive daily insulin shots by taking an easy to administer pill. However, testing of the drug exposed that an unusual number of children taking it had died. The company had employed its law firm to gather the NDA trial documentation and submit it to the FDA, and the law firm (along with a rogue Hyland employee) concealed evidence of the deaths so as to allow Hyland to reap the profits of the drug – profits that were then passed on to the firm as the company’s size and legal needs grew. Also, numerous lawyers at the firm owned part of D-Free’s patent and thus shared directly in its profits (in contravention of state bar ethics rules). While admittedly an implausible scenario, the story illustrates the wide range of options that exist for those tempted to exploit gaps in FDA drug testing law enforcement.<sup>32</sup>

#### **F. These novels portray FDA policies as stifling competition.**

In *NO*, one scientist describes how “Nobel lust” can provide the impetus for young scientists to be innovative and creative. Other novels such as *Miracle Cure* and *Flashback* focus more on the financial rewards available to those who make novel scientific discoveries, as

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<sup>32</sup> *The Price* also contains a subplot that, while not directly related to the FDA, provides interesting insights into law firm culture and its intersection with health law more generally. An ambitious young female associate at the villainous law firm, Nicki (Nicole) Maldonado, will do anything to make partner. She has given up any chance of a social life or family, as she spends every waking moment billing hours for the firm. When she is diagnosed with breast cancer, her primary concern is to preserve her chance to make partner, despite the disease. Thus, she hides her illness from her colleagues, and even pays for expensive surgery and radiation out of pocket so as to prevent the firm from finding out about her disease through her work-sponsored health insurance. But when she discovers the illegal activities the firm is engaged in surrounding D-Free, she risks her chance at partnership by attempting to expose the conspiracy, only to be murdered by one of the complicit partners. Nicki’s demise, while again perhaps implausible, illustrates the challenges young women face at male-dominated law firms, and the culture of secrecy that could hinder those in a position to prevent crimes from doing so. Moreover, because Hyland was a client of the firm, any negative information about them released by the firm could constitute a breach of the duty of confidentiality a law firm owes its clients. Nicki’s story vividly illustrates the conflicting duties a firm faces, a duty to protect the public at large by preventing crime as against a duty to zealously advocate for its own clients’ interests. *See generally* JOHNSTON, *supra* note 1.

discussed above. Regardless of its source, these novels all reveal that competition is a driving force in the scientific community. However, FDA policies are often described as stifling such innovation. For instance, in *NO*, the NDA process is described as moving more slowly for more innovative drugs, since the Agency will know less about a brand new drug's mechanisms and effects. Applications for copycat drugs that use similar principles will be processed more quickly, as the Agency will already be familiar with the chemical mechanisms involved.<sup>33</sup> An FDA tendency to take longer to approve radically new drugs provides a disincentive for drug companies to invest in developing radically new drugs, since it will be more timely and costly to do so rather than to piggyback on an existing discovery.

Yet it is worth noting that there are likely more safety concerns for a drug that differs drastically from those that have already been tested; this tendency to examine more innovative drugs more closely might be in the public's best interests despite its potential to chill scientific innovation. *Flashback* illustrated another way in which FDA regulations stifle competition: drug companies often worry that if testing drags on for too long, someone involved in the trials, or even at the FDA, will leak the discovery to competitor companies.<sup>34</sup> In *Miracle Cure*, the worry was more that competitor drug companies would lobby the FDA to deny a new drug application until they could independently formulate a competitor drug.<sup>35</sup>

In short, these novels show that FDA policies have the potential to stifle competition in various ways, which could stymie important scientific discoveries. That said, the law often places limits on competition within a marketplace, for instance with laws banning false advertising, defective products and securities regulation, and as these stories indicate, the FDA's

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<sup>33</sup> DJERASSI, *supra* note 1, at 240.

<sup>34</sup> BRAVER, *supra* note 1, at 262.

<sup>35</sup> PALMER, *supra* note 1, at 127.



mandate to protect the public safety is and should be placed above concerns about economic competition among drug companies.

## **II. FDA AS VILLAIN: INDIVIDUAL EVILDOERS**

In addition to systemic problems within the FDA regulatory scheme, these stories also suggest the possibility that individual villains within the FDA could hinder its work. There are two reasons why the FDA officials in these stories tend to fail in their duties: a) corruption, or b) political pressure.

### **A. These novels include the occasional corrupt FDA official.**

*“There was a massive cover-up underway, and what she wanted to know more than anything was who in the FDA was responsible for shutting down a legitimate investigation into what could potentially be the greatest health risk to affect the country since the AIDS epidemic.”<sup>36</sup>*

Surprisingly, corruption within the FDA was not the lynchpin of any the conspiracies described in these novels. In both *Miracle Cure* and *The Shadowbox*, low-level FDA officials are bribed by a drug company to keep test results secret. But in both cases, the crimes are brought to a screeching halt once exposed to higher authorities within the Agency. The corruption in *Capitol Reflections* is more insidious. The novel tells of a company that genetically modifies coffee beans so as to contain extra-addictive caffeine, and when the GM coffee is combined with nicotine, it causes fatal seizures. The heroine, Gwen, is an FDA employee, and when she tries to get her superiors to help her investigation, she is stalled at every turn, and is eventually fired. It turns out that many FDA officials are in on the scheme to allow the tainted coffee to enter the marketplace, and she must dodge murder at their hands in order to solve this mystery.

However, as the author points out in a post-script, the most serious problem identified by this novel is not FDA corruption, but the fact that “it is not at all clear that the genetic

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<sup>36</sup> JAVITT, *supra* note 1, at 172.

manipulation envisioned in *Capitol Reflections* is against the law... there is currently no law that requires pre-market safety review of genetically modified foods, the way there is for drugs.”<sup>37</sup>

Thus, even when FDA corruption is crucial to the plot, corruption is not the primary evil the novel seeks to identify. That none of these novels really lambast the FDA for corruption may indicate that public concern about the FDA is more focused on systemic problems within the regulatory structure. That said, the efforts of politicians and lobbyists to influence FDA decisions is indeed a grave concern in these stories.

**B. These novels often depict the FDA bowing to political pressure.**

*“The FDA doesn’t like to be told they’ve made a mistake. It’s a political organization, with people who have reputations at stake.”*<sup>38</sup>

To say that the FDA makes decisions based on politics is not necessarily a criticism. It is, after all, an administrative agency located within the executive branch, and while it operates independently, the commissioner serves at the pleasure of the President (with the advice and consent of the Senate). Thus Agency policy choices are and probably should be influenced by the current administration’s preferences. However, these novels show how the FDA’s priorities can be dangerous distorted by political pressure.

A number of these stories tell of drugs being rushed to market after a politician pressures the Agency to forgo rigorous and time-consuming testing. For instance, in *Flashback*, a doctor says optimistically, “We’re expecting the FDA to fast-track the application... Word is the president might support clinical development as a pledge to older voters in part of his reelection campaign.”<sup>39</sup> Similarly, in *Miracle Cure*, Senator Louderman of Massachusetts harshly criticizes the FDA commissioner for their delay in approving a new heart drug. The drug, not

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<sup>37</sup> JAVITT, *supra* note 1, at 413.

<sup>38</sup> JOHNSTON, *supra* note 1, at 298.

<sup>39</sup> BRAVER, *supra* note 1, 106.

coincidentally, is manufactured by a Massachusetts company that could, if it garners FDA approval, provide jobs to the senator's constituents, thereby raising his approval rating. In addition, "Louderman was angling for the Republican presidential nomination. His early public support of the drug would be a huge political coup, and somehow, profits from the drug were sure to find their way into his campaign coffers."<sup>40</sup> Thus in both *Flashback* and *Miracle Cure*, the FDA is pressured to make a decision not based on what is best for the American public, but what would better serve the careers of powerful politicians. The President has the leverage of hiring and firing power for top Agency officials, and Congress, of course, controls the FDA's purse-strings. Thus, these novels identify political pressure as a serious threat to the FDA's ability to make policy in a rational, objective manner.

But the politicians themselves are not the only source of such pressure. For instance, even once the heroes of *Capitol Reflections* have firm proof that GM coffee is dangerous, one FDA employee complains, "Issue a warning saying that drinking coffee and smoking are dangerous to your health? Assuming Americans would even care, the coffee and tobacco lobbies would be all over the government agency that will dare to float that little gem."<sup>41</sup> The industries that sell many FDA-regulated products are represented by powerful lobbying groups with strong ties to Washington. Such groups press the FDA to take positions that suit their economic interests, but the FDA's paramount concern must nonetheless be to preserve public safety.

One novel, though, suggests that FDA officials have ample incentive to keep safety concerns at the forefront of Agency priorities. When the FDA queries some of the test results submitted by the drug company in *NO*, the company's founder says, "We would save nothing by arguing with the [FDA] examiners... [they] learned a bitter lesson from the thalidomide disaster.

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<sup>40</sup> PALMER, *supra* note 1, at 70.

<sup>41</sup> JAVITT, *supra* note 1, at 392.

They get no brownie points for expediting a new drug application but could get their heads cut off if something goes wrong.”<sup>42</sup> In other words, the FDA experiences political pressure in a potentially constructive way: there is political pressure for Agency officials to do their job well. From that perspective, politics is far from an insidious distortion of FDA priorities, and more an impetus towards excellence.

### **III. FDA AS HERO**

After such a litany of complaints, it may seem as though these novels only seek to use the FDA as a punching bag for the nation’s food and drug safety woes. However, many of these novels portray the FDA as a critical vanguard of public safety, and view the problems discussed above as merely small areas in need of improvement within a generally effective agency.

#### **A. These novels portray FDA’s procedural safeguards as effective.**

*[Drug company executive:] “...all of it should be built from the start with FDA standards in mind.”*<sup>43</sup>

While, as discussed, these novels bemoan overly onerous and inefficient FDA drug testing requirements, some safeguards are revealed as highly effective. For instance, in *NO*, the drug company recognizes that “the FDA will rely on their advisory board to raise all possible scenarios that might cause problems”<sup>44</sup> with the drug. The company also recognizes that they will need to provide large sample sizes in their test submissions to the FDA.<sup>45</sup> In *Flashback*, the company realizes that if they submit honest data to the FDA, it might result in the imposition of a “black box... the warning the FDA required in a drug’s labeling – nothing a pharmaceutical

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<sup>42</sup> DJERASSI, *supra* note 1, at 130.

<sup>43</sup> *Id.* at 82.

<sup>44</sup> *Id.* at 148.

<sup>45</sup> *Id.* at 151.

company welcomed.”<sup>46</sup> FDA procedures such as the imposition of warning labels or large clinical trial sample sizes are thus portrayed as effective limits on what drug companies can get away with.

It is important to recognize that these novels seek primarily to entertain, and only incidentally to educate, their readers. Effective, well-functioning Agency procedures would likely present less thrilling material than dysfunctional practices. Therefore, the comparative frequency of FDA mismanagement in these novels as compared with Agency success stories could be attributed simply to the authors’ desire to entertain readers, not any major failing on the part of the Agency.

**B. These novels portray FDA policies as pushing dangerous food and drug production practices out of US territory.**

*[Says gangster:] “Boiled down... the FDA has become a ... powerful bully with standards that are considered absurdly rigorous by every other developed country.”*<sup>47</sup>

The FDA’s attention is focused on the American market. Many of these novels discuss how the rigor of FDA standards has pushed drug development work abroad. This is sometimes merely the result of the higher costs incurred by conducting research in America, as a drug company executive explains in *NO*: “Of course, we had to raise a fair amount of money (though only a fraction of what it would have cost to do the same [drug development] work in the States, rather than Israel).”<sup>48</sup> While perhaps a concern from an economic perspective, since the pharmaceutical industry creates less American jobs if it operates overseas, this problem is no more insidious in the food and drug context than in any other, and outsourcing has of course become common for many products and services.

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<sup>46</sup> BRAVER, *supra* note 1, at 347.

<sup>47</sup> MAXIM, *supra* note 1, at 321.

<sup>48</sup> DJERASSI, *supra* note 1, at 97.

Yet these novels also describe a more nefarious reason companies develop drugs abroad: avoidance of FDA safety standards. The reason for developing drugs abroad, notes a lawyer in *The Shadowbox*, is “the freedom from burdensome controls. Some [countries] have no standards at all concerning product contamination, safety in the workplace, or even disposal of toxic waste.”<sup>49</sup> Similarly, the dangerous GM coffee at issue in *Capitol Reflections* was grown in South America and offshore in Hawaii, in an attempt to avoid FDA scrutiny. Another popular fictional depiction of such a move overseas is found in the popular John le Carré novel *The Constant Gardener*.<sup>50</sup> In that story, a drug company tests a new tuberculosis drug on unwitting subjects in Africa, so as to skirt the costs and safety requirements imposed by the FDA and similar agencies in other developed countries.

The shifting of dangerous food and drug production abroad results in human tragedies. But, arguably, this migration is proof that the FDA is doing its job. If FDA sets standards that prevent companies from jeopardizing public health for profit in America, surely it has accomplished its mandate. This is not to advocate a “not in my backyard” global perspective, but merely to emphasize that the FDA’s jurisdiction does not extend worldwide, and it is important to place reasonable limits on its goals. Further, if other countries can regard the FDA as a model, it is more likely that they will follow the Agency’s lead and eradicate dangerous drug testing practices from their own jurisdictions, via the creation of analogous agencies.

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<sup>49</sup> MAXIM, *supra* note 1, at 127.

<sup>50</sup> JOHN LE CARRÉ, *THE CONSTANT GARDENER* (2000).

### **C. These novels portray the FDA as effectively working in tandem with the media.**

*“And the reporter?” asked Wallace Pembroke, [corrupt] chairman of the Federal Reserve Board in his raspy voice.  
“He’s the wild card.”<sup>51</sup>*

The FDA does not operate in a vacuum, and many of the Agency’s successes, as presented in these stories, result from the FDA working in conjunction with the media. Media exposure of drug-related crimes plays a key role in the villains’ downfall in many of these books. In *Capitol Reflections*, the ill-intentioned GM coffee purveyor technically adheres to all applicable laws, but its executives realize that public exposure of their practices would lead to widespread outcry and boycotting of their GM coffee product. The two heroes of the book, Gwen as FDA epidemiologist and Mark as *Washington Post* reporter, are a perfect team for dismantling the GM food empire the evil coffee company has assembled.

The media play a different role in *Miracle Cure* and *Flashback*, namely to pressure the FDA to approve a drug as quickly as possible. A TV news segment in *Miracle Cure* excitedly announces that “the President will travel to Boston in just two days to preside over ceremonies approving the Boston-developed and -tested drug Vasclear.”<sup>52</sup> With that sort of reporting, it is easy to see how the Agency might be hesitant to deny the drug’s application, based on the evidence the hero is desperately trying to bring to their attention. Similarly, in *Flashback*, after Memoline is (temporarily, as it turns out) approved, the drug company holds a gala, and in attendance are “representatives from different Alzheimer’s organizations, the FDA, the state legislature, Capitol Hill, and, of course, the White House.” After such a high-profile public event, it would be difficult for the FDA to about-face and deny the application. But they do just that, and “the director of the FDA said that [the application’s denial] was medical progress. ‘This

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<sup>51</sup> JAVITT, *supra* note 1, at 407.

<sup>52</sup> PALMER, *supra* note 1, at 315.

initiative is going to push drug companies to be more thoughtful when testing their products and not rush them to market or cover up damaging evidence.’ ”<sup>53</sup>

In sum, these novels show the FDA as working with the media to publicize crimes so as to deter further wrongdoing, and the Agency does not seem to shy away from unpopular decisions even in the glare of the media spotlight.

#### **IV. FICTION AS LENS FOR THE STUDY OF FOOD AND DRUG LAW**

*“[T]his book began as a work of fiction. I can only hope that it remains so.” – Jonathan Javitt, Capitol Reflections, Author’s Note*<sup>54</sup>

The seven novels discussed here raise many of the key issues at play in food and drug law today. That said, of course, any student of food and drug law must study actual statutes, regulations and cases. But fiction can provide a useful supplement to traditional legal analysis in the food and drug area, for three reasons: a) fiction can serve as a reminder as to how the regulation of food and drugs affects Americans in the most personal of ways, b) novels can render complicated FDA practices and procedures comprehensible to the layperson, and c) much of what is described in these novels is not far from reality.

##### **A. Fiction exposes the personal dramas inherent to food and drug regulation.**

*“Luke sat on the couch with his arm around his daughter... ‘I hate sticking my finger, Daddy. With D-Free I don’t have to.’ ”*<sup>55</sup>

These stories underscore the grief and joy that can result from new medications in a way that regulations or statistics cannot. Students of food and drug law typically read cases that have come before the courts. Such cases necessarily involve a specific conflict, or story, wherein the litigants disagree over some aspect of food and drug regulation. These cases could raise personal

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<sup>53</sup> BRAVER, *supra* note 1, at 399.

<sup>54</sup> JAVITT, *supra* note 1, at 14.

<sup>55</sup> JOHNSTON, *supra* note 1, at 137.



issues, such as a class action suit filed against a drug company whose products injured the plaintiffs, or, could be more administrative in nature, such as a company filing suit to challenge FDA nutrition labeling requirements. In either situation, the judicial opinion that resolves the case will focus, as it should, on the legal framework that surrounds the issue. Fiction, in contrast, focuses on the stories and concerns of the characters, which, in these stories are mostly those who could be litigants in court for food and drug claims. The legal framework is discussed only insofar as it is relevant to the characters' lives. Fiction thus can provide a useful counterpoint and supplement to traditional legal analysis.

For example, in *The Price*, hero Luke Creed is a lawyer at the firm representing Hyland Pharmaceuticals, a company that manufactures the diabetes drug D-Free. Luke's young daughter, Brynne, is diabetic, and unbeknownst to Luke, his ex-wife has been administering D-Free to Brynne for months.<sup>56</sup> Meanwhile, Luke's work defending Hyland against wrongful death suits filed by D-Free users has revealed that the drug is dangerously flawed. These facts alone do not offer readers of *The Price* any more insight than one would glean from reading a judicial opinion the wrongful death suit, were it a real case. But Luke's story raises a more subtle issue that is relevant to the FDA's work, and that might not be illuminated so vividly in traditional legal texts such as caselaw: even after his ex-wife learns that D-Free could be dangerous, she continues to give it to her daughter Brynne. Even Luke, who has proof of the drug's harm, decides not to forbid Brynne from taking it, after she says to him plaintively: "I love D-Free, Daddy...I haven't

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<sup>56</sup> This aspect of the story raises interesting issues involving the intersection of food and drug law with family law. As a parent with joint custody, Luke is legally permitted to share control over his daughter's medical treatment. But in reality, his ex-wife Valerie was able to hide the prescription from him, and he has no interest in causing the intrafamilial strife that would result if he took her to court over this. The reader gets a sense of Luke's frustration and anguish as he realizes that despite what the law says, he is essentially powerless at protecting his daughter against this dangerous drug, so long as Valerie wants her to take it. *See generally* JOHNSTON, *supra* note 1.

had to take a shot for 3 whole months. I feel... normal.”<sup>57</sup> Like any flawed drug, this pill does not harm everyone who takes it, in fact, far from it. Side effects are few and far between, although very serious when they occur. *The Price* illustrates something a statute or statistics could not: the heartbreaking nature of the dilemma faced by those desperate for a cure for their ailments, and willing to take some risks to obtain it.

Similarly, it is worth revisiting a quote discussed earlier in this paper<sup>58</sup>, from *Capitol Reflections*. “Issue a warning saying that drinking coffee and smoking are dangerous to your health? *Assuming Americans would even care*, the coffee and tobacco lobbies would be all over the government agency that will dare to float that little gem.”<sup>59</sup> The introductory phrase, “assuming Americans would even care,” raises an issue that is implicated by Luke Creed’s dilemma about whether to permit Brynne to take D-Free: what level of risk are we willing to take, when our health is at stake? The large number of people who still smoke cigarettes is testament to the serious risks Americans are willing to take so as to lead a pleasurable life. The level of risk acceptable to consumers is likely higher when the potential reward is not merely a small pleasure such as a cigarette, but instead the possibility of curing disease. For instance, in *Miracle Cure*, Dr. Brian Holbrook is desperate for his father to be accepted a participant in clinical trials for a new, experimental heart drug. He knows the drug is risky (though just how risky, he does not discover until the end of the novel), but he is willing to take the risk if it might save his ailing father’s life. In sum, through characters such as Luke Creed and Dr. Brian Holbrook, readers can get a sense of the complexity of the FDA’s challenge: the Agency must protect a public who will not always act to protect themselves.

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<sup>57</sup> *Id.* at 98.

<sup>58</sup> *See supra*, page 18.

<sup>59</sup> JAVITT, *supra* note 1, at 392 (emphasis added).

## **B. Fiction renders FDA policies and procedures comprehensible to the layperson.**

The majority of these seven novels constitute “popular” as opposed to “literary” fiction, meaning that the intended audience is the average layperson, not a reader with vested interest in food and drug law or highbrow, acclaimed prose. Such readers would be unlikely to parse FDA rulemaking announcements or the Food, Drug and Cosmetic Act, and these books allow these readers to garner an extremely detailed knowledge of FDA procedures nonetheless. If the average American, i.e. not a lawyer or law student, wanted to learn about the current regulatory structure surrounding food and drugs, they would be hard-pressed to understand it by reading the text of the Food, Drug and Cosmetics Act or FDA regulations. But fiction can provide quite a detailed and accurate explanation of FDA procedures and practices, and can reach an audience that would be unlikely to scour the federal register for new regulations or federal reporters for new cases.

Appendix B contains sales data for these seven books. While at first glance these figures might seem dispiriting (the most successful of the seven only reports approximately 98,000 copies sold), these seven titles represent only a few examples of many books on the market that likely delve into FDA practices in similar depth. Often, such books are published as “mass market” paperbacks (including *The Price*, *The Shadowbox*, and *Miracle Cure*), the small-size format typically denoting that a book aims for a wide commercial audience, as opposed to a more rarified subset of the reading populace. Carl Djerassi states in his author’s note preceding *NO*, “I am attempting to narrow the ever-widening gulf between the scientific community and the other subcultures of contemporary society – the arts and humanities, the social sciences and, most strikingly, the culture at large.” The novels discussed here, including *NO*, successfully narrow this gulf. These books and others like them increase public awareness of FDA practices.

At a time where politician and voters are vigorously debating the appropriate size and role of government, the public's perception of an agency such as the FDA is important, as trust in such an agency could lead voters to support politicians who favor more regulation, and thus more funding for such agencies. Fiction, therefore, can play a not insignificant role in shaping the views and votes of the electorate.

**C. The fictional stories presented in these novels may hew close to reality.**

These books are works of fiction, and this paper only seeks to analyze them as such. However, after reading these novels, the first question a reader will likely ask is how close to reality the stories hew. While, as discussed, these books contain much realistic and useful information about the FDA, the central plots are admittedly quite fantastical. This observation is not intended as criticism, since the authors, after all, set out to write compelling fictional stories, not informational treatises about the FDA. With the exception of *NO*, which sought to portray the founding of a biotech company as realistically as possible, the plots hinge on implausible scenarios such as major drug conglomerates controlled by violent gangsters (*The Shadowbox*), robot-controlled humans taking over the world (*Small Miracles*), or the existence of a jellyfish venom-derived chemical that cures Alzheimer's disease (*Flashback*).

Yet each story also raises more realistic concerns. In fact, three out of seven of these authors include notes to the reader addressing the realism of their work, which provide a means of assessing, in broad strokes, how much readers can learn about reality from these fictional works. Of these seven books, the scientific discovery at issue in *Small Miracles* seems the least realistic. Nanotechnology, while commonplace in the world of computer science, does not seem likely to advance such that microscopic nanobots will infiltrate human brains, develop consciousness, and proliferate. Yet author Edward Lerner states in a prefatory note, "In the near

future, complex machines smaller than individual biological cells – and with the potential, therefore, to access, diagnose, and treat any cell in our bodies – will revolutionize medical practice. I defer to the story for examples.”<sup>60</sup> This possibility is intriguing, and its implications for the FDA far-reaching. As Jonathan Javitt states in his author’s note: “When it comes to food safety, the FDA is hampered by a limited scientific workforce and a body of law that was written in the fifties and sixties, long before today’s science of genetic manipulation was ever imagined.”<sup>61</sup> Javitt’s comments come in the context of GM food, not nanotechnology, but the two authors seek to make a similar point: their novels expose a real-life problem, namely that the FDA’s laws and enforcement tactics must adapt to changing technology in order to implement effective regulatory policy in these modern times.

In addition to the challenge of regulating rapidly advancing technology, these novels show how the FDA’s regulatory program might be more effective on the drug side than with regards to food. As Jonathan Javitt says in his author’s note: “Clearly, the actions depicted in this story are illegal and reprehensible. With that said, they have become increasingly plausible as the science for genetic modification of foods rapidly overtakes our ability to implement regulatory safeguards.”<sup>62</sup> Complaints about FDA bureaucracy, a common theme in the drug-related novels discussed here, are absent in *Capitol Reflections*, and the book’s aim is to expose the dearth of regulation when it comes to food, especially when contrasted with drugs. Such a concern seems not unfounded, given the many recent health scares involving food<sup>63</sup>, and through reading

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<sup>60</sup> LERNER, *supra* note 1, at 5.

<sup>61</sup> JAVITT, *supra* note 1, at 414.

<sup>62</sup> *Id.* at 412.

<sup>63</sup> See, e.g., William Neuman, *Egg Farms Violated Safety Rules*, N. Y. TIMES, Aug. 31, 2010, at B10.

*Capitol Reflections*, readers get a feel for the FDA's practices in regard to food regulations, and the loopholes that could be worrisome in the unfolding age of GM food.<sup>64</sup>

While billed as a novel, the author's note preceding *NO* states that Carl Djerassi intended it as "science-in-fiction," as opposed to science fiction. He explains that "no significant aspects of the newly discovered biological properties of NO [the chemical compound at issue in the book] are made up. Nor, for that matter, is the conduct of the various scientific protagonists, entrepreneurs, and lawyers." Readers of *NO*, thus, receive a lesson about FDA regulatory practice, in the guise of a novel. Djerassi himself, as one of the inventors of the birth control pill, has ample experience to draw upon. Out of these seven novels, then, Djerassi's paints the picture that is closest to reality. But as evidenced by the above discussion, plot veracity is not a prerequisite for providing readers with valuable information about food and drug law, and all of these novels contain useful information about the current legal framework surrounding food and drugs.

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<sup>64</sup> Javitt's author's note contains many other interesting observations, including the following: "[I]t is not at all clear that the genetic manipulation envisioned in *Capitol Reflections* is against the law in any way. Those skilled in FDA regulatory law may take issue with Lane Chase's final comment that d-caffeine could not be regulated. Obviously, were the FDA to determine that a food, even a naturally occurring food, posed a major health hazard, FDA has ample regulatory authority to force that product off the market, even if it has to seize the product at the store... In this case, however, ... [a]lthough the d-caffeine was certainly addictive, it's not clear that without deliberate manipulation it was hazardous to the point where FDA could have forced it off the market on public safety grounds without a major battle. Certainly, there are those who might argue the theory that inserting a gene for d-caffeine constitutes the addition of a food additive not generally recognized as safe. This theory has been used voluntarily by at least one company that successfully sought FDA approval to bring a rot-resistant tomato to market for human consumption. The fine points will likely be debated in law school classes and law review articles until Congress clarifies the issue... While the story is fictional, much of the background is not... the definitions of 'adulterated food,' which is the primary tool the FDA has for enforcement, certainly doesn't contemplate such a manipulation." JAVITT, *supra* note 1, at 413-14.

## **Conclusion**

In conclusion, these seven novels portray the FDA as both villain and hero, and expose many of the most important policy choices the Agency faces today. In addition, readers of these books get a more personal perspective on food and drug law issues than traditional legal analysis could provide. Fiction can serve an important informative function to a segment of the public that would likely find legal texts such as regulations, statutes or cases too dry and narrowly focused to provide the kind of big-picture view of food and drug law these novels provide.

It is important not to lose sight of the fact that these novels, while serving an important function in their ability to inform and educate readers, also accomplish a more basic goal: entertainment. As shown in the plot summaries that follow, and in the sales figures succeeding them, these seven books have entertained tens of thousands of readers, surely a laudable accomplishment in its own right. Readers will have gained substantial knowledge about the FDA and its practices, and these novels allow them to do so in a way that is easy, quick, and perhaps most importantly, fun.

## **APPENDIX A: PLOT SUMMARIES**

Note: Many of these plots were quite intricate, but I have focused here on aspects involving the FDA or food and drug law more generally.

### **The Price by Joan Johnston<sup>65</sup>**

Luke Creed is a lawyer at a large Houston law firm. He is assigned to defend a drug company, Hyland, in a wrongful death suit relating to their diabetes pill, D-Free, which replaces the insulin injections diabetics usually need. Luke's daughter Brynne suffers from diabetes, and begins taking D-Free. Luke begins to investigate the case, along with opposing counsel (and former flame) Amy. They discover that four other wrongful death cases have been filed, and that there were many deaths during the clinical testing. It turns out that lawyers at the firm, who had been charged with passing along the clinical results to the FDA, doctored them so as to hide the deaths. Anyone who caught wind of the plan was murdered, and Luke and Amy must keep their wits about them as they face violent attempts on their lives. Hyland, when alerted of their lawyers' deception, withdraws D-Free from the market pending modification, FDA retesting and re-approval.

### **The Shadowbox by John R. Maxim**

Michael Fallon is an investment banker who specializes in drug company stocks, including a large drugmaker, AdChem. Murder seems to follow Michael, as many of his family members, and then his fiancée, are all murdered. It turns out AdChem is involved in the counterfeit drug market. Michael attempts to flee the whole situation and lead a quiet life on Martha's Vineyard, leaving pharmaceutical companies, corruption and murder behind. The FDA

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<sup>65</sup> Generally I have strived to avoid literary criticism in this paper, and assessed these books based on what they discuss, not how they discuss it. However it is worth noting that of the seven books discussed here, *The Price* was, in my opinion, the most entertaining read.



has been bought out by AdChem and so isn't doing anything to stop these crimes. But the gangsters involved with the scam, as well as the complicit bankers at Michael's old firm, think he knows too much, and try to kill him and his new girlfriend Meghan. Just in time, he uncovers their scam, and tells the FDA he won't uncover the corruption within Agency ranks if they promise to enforce laws to prevent the counterfeit drugs from reaching the market.

### **Small Miracles by Edward Lerner**

This novel is set in 2016. Brent is a salesperson at a company that manufactures nanobot suits, which, upon injury to the person inside, inject "nanobots" into the bloodstream to deliver whatever the damaged cells need. The U.S. Army has placed a large order for the suits, pending FDA approval. While wearing the suit for a sales pitch to a police department, Brent is seriously injured in a gas pipeline explosion. The nanobot suit saves his life, and he becomes an accidental participant in the ongoing clinical studies about nanobots. An unforeseen development arises when the nanobots, far from dissipating once they have administered medical treatment at the cellular level, actually develop a consciousness and take over the brain of their victim. Once infiltrated, Brent is controlled by the nanobots, and he purposely injects many of his coworkers with nanobots so that they, too, are under the bots' control. Meanwhile, Brent's friend and coworker Kim is trying to figure out what's going on. They try to call in the FDA to halt the trials, but they are too late – the evil nanobot-controlled humans, led by Brent, have taken over the nanobot suit factory. Just in time, they discover the details of the nanobots' plot and foil it, preventing the widespread takeover of the human race. Clinical testing for nanobots is never completed.

### **Flashback by Gary Braver**

René Ballard is a pharmacist consultant. One of her nursing home patients, an elderly lady stricken with Alzheimer's, escapes and commits murder. Meanwhile, Jack Koryan is brutally attacked by a swarm of rare jellyfish while swimming in the ocean. It turns out that the nursing home, along with many others across the country, is conducting trials for a drug called Memorine, of which the active ingredient is also found in the jellyfish venom now in Jack's bloodstream. Both Jack and the test participants begin to experience flashbacks – vivid and dangerous hallucinations of youth. The FDA was initially very excited about the drug, and there was political pressure to get it approved, coming straight from the president. The drug company will do anything to prevent the side effects from becoming known, including murder. The FDA approves the drug. However, René and Jack survive much violence, and convince some of the doctors on the team to tell the FDA the truth, and the new drug application is consequently withdrawn.

### **Miracle Cure by Michael Palmer**

Dr. Brian Holbrook is a cardiologist attempting to restart his life after a battle with prescription painkiller addiction. When he returns to work at the Boston Heart Institute, he learns of a new drug that is being tested, Vasclear, claimed to be a miracle heart drug. It turns out that the Vasclear NDA trial results are being faked – most of the patients with success stories never had heart problems in the first place, and the drug hurts many other participants. The drug's developer knows this, but has invested \$100 million developing the drug and want to sell enough to break even before the anomalies become known and the FDA yanks it from the marketplace. Those who threaten to reveal this plot to the FDA are murdered, and a number of doctors at the hospital are complicit in the scheme. Brian secretly runs some experiments to prove that

Vasclear is ineffective, and he contacts the FDA. But the FDA official he contacts (and in fact has a romantic affair with) has been bribed, and so fails to take any action. But Brian remembers that even though the corrupt doctors destroyed most of the evidence that Vasclear doesn't work, there are still some test results locked away: those of Walter Louderman, a senator from Massachusetts, where the drug company is based. Senator Louderman had been putting pressure on the FDA to fast-track this drug, so as to improve his political standing in his home district. When Brian realizes that Louderman's own heart records and Vasclear trial results have not been destroyed, he manages to dodge many murder attempts and expose the plot.

### **Capitol Reflections by Jonathan Javitt**

Gwen is an FDA epidemiologist. When her best friend Marci dies of an inexplicable seizure, Gwen consults MedWatch, the FDA's "adverse event" tracking system, and discovers a pattern of seizure activity across the nation. Using this database and other FDA statistical tools, Gwen discovers that the seizures all occur near a branch of the popular coffee megachain Pequod's. Analysis of the victims uncovers that they all drank Pequod's coffee and smoked cigarettes just before their fatal seizure. Along with her old flame Mark, now a reporter for the *Washington Post*, Gwen seeks to get to the bottom of the mystery. But when her superiors at the FDA find out what she is doing, she is fired. It turns out that Henry Broome, a powerful senator, stole a GM coffee plant from his college roommate years ago, and he has extensively planted and harvested the special bean, and convince Pequod's to use it in their brews. The GM coffee contains a special kind of caffeine that is incredibly addictive, and thus lucrative. When combined with nicotine, though, it causes seizures. Broome uses his political pressure to prevent the confirmation of an FDA commissioner seeking to curtail the sale of GM foods, and he also buys the silence of key FDA employees. But Gwen and Mark discover the plot, and after

dodging murder attempts, they manage to inform the Attorney General. While the FDA does not take action against Pequod's since GM food is legal, the threat of public exposure convinces the company to stop using the GM coffee. Gwen is promoted to deputy commissioner of the FDA, Senator Broome commits suicide, the corrupt FDA agents are thrown into prison, and a public health crisis is averted.

### **No by Carl Djerassi**

This book, billed by the author as “science-in-fiction,” tells the story of a biotech start-up from the moment the drug is developed through the company's IPO. Dr. Renu Krishnan, the protagonist, is a female Indian scientist, married to an Israeli colleague. They both work on fertility treatments. Renu and her team discover a new erectile dysfunction drug, and the novel provides an in-depth discussion of NDA testing requirements. It also focuses on financial matters; the IPO happens before the FDA application is approved, and Renu struggles to find investors to fund the drug's trials. The company's success hinges on FDA approval. Renu and the rest of the company's board members find themselves the target of a shareholders' derivative suit, based on comments about the FDA trials made by Renu to a reporter, but the case eventually falls apart. In the end, Renu decides to sell her share of the company and return to the lab to conduct new research, but the company is a success and its erectile dysfunction drug has made it onto the market.

## **APPENDIX B: SALES FIGURES**

The source of the below numbers is BookScan, a book sales data-gathering service widely used in the publishing industry. These numbers constitute the best available data for sales of these titles. However, they are not completely accurate for three reasons. First, BookScan does not track consumers' purchases from bookstores, but instead, bookstores' purchases from publishers. How many consumers actually purchased is likely similar, though not identical. Second, these numbers exclude all used book sales and library borrowings. Third, BookScan figures are less reliable for older titles (such as *NO*, *Miracle Cure* and *The Shadowbox*) and titles released by small publishers (such as *NO*). Thus, all in all, these numbers are likely significantly lower than the true sales numbers. That said, they convey a sense of the approximate size of each book's readership.

<b><u>Title</u></b>	<b><u>Hardcover Sales</u></b>	<b><u>Paperback Sales</u></b>
<u>The Price</u> by Joan Johnston (Atria, 2003)	14,275	83,423
<u>The Shadowbox</u> by John R. Maxim (Avon, 1996)	No data – but publisher notes a 50,000 first printing for the hardcover edition. <sup>66</sup>	7,016
<u>Miracle Cure</u> by Michael Palmer (Bantam, 1998)	43 [likely inaccurate]	17,026
<u>No</u> by Carl Djerassi (Univ. of Georgia Press, 1998)	11 [likely inaccurate]	368 [likely inaccurate]
<u>Flashback</u> by Gary Braver (Forge, 2005)	2,564	2,388
<u>Capitol Reflections</u> by Jonathan Javitt (Sterling and Ross, 2008)	212	1,169
<u>Small Miracles</u> by Edward Lerner (Tor, 2009)	452	1,659

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<sup>66</sup> Publishers' Weekly review, *available at*:  
[http://www.amazon.com/gp/product/0380973006/sr=1-1-1/qid=1300310230/ref=sr\\_1\\_1\\_oe\\_1?ie=UTF8&s=books&qid=1300310230&sr=1-1](http://www.amazon.com/gp/product/0380973006/sr=1-1/qid=1300310230/ref=sr_1_1_oe_1?ie=UTF8&s=books&qid=1300310230&sr=1-1)